

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

JOHN C. MEAD)	
)	
Plaintiff,)	
)	
v.)	No. 4:05-CV-01558 CEJ
)	
SYNTHES SPINE COMPANY, L.P.,)	
et al.,)	
)	
Defendants.)	

MEMORANDUM AND ORDER

Plaintiff brings this action against defendants Synthes Spine Company, L.P. and Synthes U.S.A., alleging that surgical screws manufactured and sold by defendants and implanted in plaintiff's spine were defective, resulting in plaintiff's injury. Defendants move for summary judgment, pursuant to Rule 56, Fed. R. Civ. P. Plaintiff opposes the motion, and the issues are fully briefed.

I. Legal Standard

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment shall be entered "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." In ruling on a motion for summary judgment the court is required to view the facts in the light most favorable to the non-moving party and must give that party the benefit of all reasonable inferences to be drawn from the underly-

ing facts. AgriStor Leasing v. Farrow, 826 F.2d 732, 734 (8th Cir. 1987). The moving party bears the burden of showing both the absence of a genuine issue of material fact and its entitlement to judgment as a matter of law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986); Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986); Fed. R. Civ. P. 56(c). Once the moving party has met its burden, the non-moving party may not rest on the allegations of his pleadings but must set forth specific facts, by affidavit or other evidence, showing that a genuine issue of material fact exists. Fed. R. Civ. P. 56(e). Rule 56(c) "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

II. Background

Plaintiff began experiencing severe back pain in early 2001 following a back injury he sustained while building a fence for his employer. Plaintiff initially pursued a variety of non-surgical treatments for the pain, including chiropractic treatment, prescription painkillers, and epidural steroid injections, but these treatments did not relieve his pain. In July 2004, plaintiff again injured his back in a workplace accident and was referred to

Timothy Graven, M.D. Dr. Graven diagnosed plaintiff with degenerative disc disease at L5-S1 of his vertebral column.¹

Dr. Graven suggested that plaintiff could undergo Anterior Lumbar Interbody Fusion Procedure, an operation in which the surgeon would remove the intervertebral disk, install a metal cage to replace it, and implant an Anterior Tension Band System ("ATB system") at L5-S1. The ATB system included a metal plate fastened to the vertebrae with four Titanium Cancellous Locking Screws manufactured and sold by defendants. The purpose of the ATB system was to restrict motion in the lower portion of plaintiff's spine to promote bone fusion at the L5-S1 vertebrae. The ATB system also was intended to hold the intervertebral metal cage in place.

Dr. Graven performed the surgery on December 6, 2004. X-rays of plaintiff's spine taken on December 14, 2004, and on January 14 and February 11, 2005 revealed that the ATB system was in good position. However, on February 11, 2005, plaintiff complained that his back pain was as severe as before the surgery. A CT scan and lumbar myelogram² performed on March 1, 2005 confirmed that the ATB

¹ L5-S1 refers to the fifth lumbar and first sacral vertebrae; the five sacral vertebrae form the base of the vertebral column of the spine. PDR Med. Dict., 2d ed. (2000), 1956-57.

² A myelogram is a "[r]adiographic contrast study of the spinal subarachnoid space and its contents." PDR Med. Dict., 2d ed. (2000), 1171. Radiography is the "[e]xamination of any part of the body for diagnostic purposes by means of x-rays with the record of the findings usually impressed upon a photographic film." Id. at 1504.

system was in good position. Plaintiff reported that his back pain was still very severe.

On June 10, 2005, an x-ray of plaintiff's spine revealed that the four screws implanted in the ATB system had fractured at close to mid-length of the screw shafts. Despite the fractures, the x-rays revealed that the screws were still attached to the vertebrae and the plate had not loosened. Further x-rays on October 28, 2005 showed that the fractured screws had not loosened from the bone and continued to hold the plate in place.

By July 2005, limited bone fusion had taken place, but in an effort to promote better fusion and relieve plaintiff's pain, on August 17, 2005, Dr. Graven performed a second operation on plaintiff. Dr. Graven testified that the second surgery was precipitated by plaintiff's continuing pain and the failure of his vertebrae to fuse satisfactorily, and not by the fracture of the screws. Following the second surgery, plaintiff continued to experience back pain, and as of the last time Dr. Graven examined him, plaintiff's vertebrae had not fused sufficiently to prevent significant continuing pain.

III. Discussion

Plaintiff alleges that four screws manufactured and sold by defendants and implanted into his spine were defective and that their fracture caused him injury. Defendants assert in their motion that plaintiff has not produced any evidence that the screws

fractured because they were defective or that the fractures were the proximate cause of plaintiff's injuries. Defendants argue that plaintiff has not established that the screws were unreasonably dangerous or defective when sold. Defendants maintain that while circumstantial evidence may be presented allowing the jury to infer the existence of a defect, the plaintiff must present evidence eliminating other potential causes of the injury to discourage the jury from improperly speculating as to causation. Defendants state that plaintiff has failed to eliminate other potential causes of plaintiff's injury.

This case arises under the Court's diversity jurisdiction, and thus Missouri law applies. Under Missouri law, the plaintiff must prove as an essential element of negligence or strict liability that "the defect in the product or the negligence of the manufacturer was the proximate cause of the injuries sustained by the plaintiff while he was using the product in a reasonably intended manner." Willard v. Bic Corp., 788 F.Supp. 1059, 1063 (W.D. Mo. 1991), citing Garrett v. Jos. Schlitz Brewing Co., 631 S.W.2d 652, 654 (Mo. Ct. App. 1982). "The existence of a defect in a product may be inferred from circumstantial evidence, with or without the aid of expert testimony." Aetna Cas. & Sur. Co. v. General Elec. Co., 758 F.2d 319, 322 (8th Cir. 1985), citing Williams v. Deere & Co., 674 S.W.2d 609, 612 (Mo. Ct. App. 1980).

To prove a product liability claim by inference from circumstantial evidence without proof of a specific defect, a plaintiff must offer evidence that (1) tends to eliminate

other possible causes of the injury . . . (2) demonstrates that the product was in the same basic condition at the time of the occurrence as when it left the hands of the defendants, and (3) the injury or damage is of a type that normally would not have occurred in the absence of a defect in the product.

Hickerson v. Pride Mobility Products, 470 F.3d 1252, 1258 (8th Cir. 2006), citing Fain v. GTE Sylvania, Inc., 652 S.W.2d 163 (Mo. Ct. App. 1983), and Lindsay v. McDonnell Douglas Aircraft Corp., 460 F.2d 631 (8th Cir. 1972).

If the injury may have resulted from one of two causes, for one of which, and not the other, the defendant is liable, the plaintiff must show with reasonable certainty that the cause for which the defendant is liable produced the result; and, if the evidence leaves it to conjecture, the plaintiff must fail in his action.

Willard, 788 F.Supp. at 1066, citing Zafft v. Eli Lilly & Co., 676 S.W.2d 241, 244 (Mo. banc 1984).

Plaintiff's designated as his sole expert witness Dr. Graven, plaintiff's treating surgeon. In his deposition, Dr. Graven testified that the screws implanted in plaintiff's spine fractured some time between March 10 and June 10, 2005. Dr. Graven reported that plaintiff experienced mild temporary improvement in his condition immediately following the first surgery in December 2004, but the pain later returned. By March 10, 2005, and as of his last examination of plaintiff in or after October 2005, Dr. Graven found that plaintiff was experiencing significant back pain. Dr. Graven testified that the plaintiff's two surgeries had not successfully relieved his pain. Dr. Graven testified that he did not believe that the return of plaintiff's back pain to pre-surgery levels was

caused by the condition of the implanted plate and screws. Dr. Graven testified he did not know why the surgeries had not succeeded, but that the lack of success was not atypical for such operations.

Dr. Graven testified that he normally tells back surgery patients that they could expect a 50 percent improvement in their condition following surgery, but that there is a risk that bone fusion will not occur. Dr. Graven also testified that any medical device made of metal "has a finite life," and if the bone does not fuse, such devices "will fail." Graven Dep. at p. 12. The medical goal of using such devices is to "stabilize the bone or the structure until such time as a fusion or solid bone healing takes place so that the fusion takes place prior to that metal fatiguing and fracture." Id. The risk of non-fusion is forty percent greater in patients who smoke than in those who don't. Dr. Graven testified that he gave this information to plaintiff, who had a 14-year history of smoking a pack of cigarettes a day.

Dr. Graven testified that his specialty was in using orthopedic devices, not in manufacturing, designing or testing them. He further testified that he had no expertise in metallurgy, biomechanics, or engineering. Dr. Graven and defense counsel then had the following exchange:

Q [Defense counsel]. Are you in a position to testify to a reasonable degree of engineering medical certainty that these screws were defective?

A [Dr. Graven]. No, I don't know the cause of the failure of the screws.

Q. All right. As you say, anytime you put medical devices in people, they are subject to fracture?

A. That's always a possibility, yes.

Graven Dep. at p. 39.

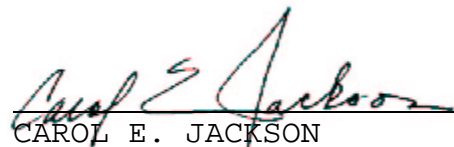
The Court finds that the plaintiff is unable to establish that the fracture of the screws was the result of a defect in their design or manufacture. Indeed, plaintiff's sole expert witness, Dr. Graven, admitted that he did not know the cause for the screws' failure, and that he lacked the expertise to make such a determination.

Additionally, plaintiff has not presented sufficient circumstantial evidence from which a jury could infer the existence of a defect. Hickerson, 470 F.3d at 1258. According to plaintiff's expert, it is well-known that the devices will fail if fusion does not occur. Dr. Graven further acknowledged that smokers, such as plaintiff, presented a higher risk of non-fusion. The evidence also establishes that plaintiff had not fused by the time the screws fractured, and that he had collapsed before the fractures were discovered. Plaintiff has offered no evidence that tends to eliminate possible causes of the injury other than the alleged defect of the screws, nor has he presented evidence that the fractures of the screws would not normally occur in the absence of a defect.

After viewing the evidence in the light most favorable to the plaintiff, the Court finds that as a matter of law, plaintiff cannot establish an essential element of his products liability claim. The defendants are, therefore, entitled to judgment as a matter of law.

Accordingly,

IT IS HEREBY ORDERED that the motion of defendants Synthes Spine Company, L.P. and Synthes (U.S.A.) for summary judgment [#50] is **granted**. A separate judgment in accordance with this Memorandum and Order will be entered this same day.


CAROL E. JACKSON
UNITED STATES DISTRICT JUDGE

Dated this 22nd day of May, 2007.